K131634

510(k) Summary
as required by 21 CFR Part 807.92(c)

Identification of the Submitter

Submitter:	Elaine Chang, RAC Regulatory Technical Specialist Siemens Medical Solutions USA, Inc. 810 Innovation Dr Knoxville, TN 37932 USA
Telephone Number:	(865) 218-2873
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Name / Address of Manufacturer:	Siemens Medical Solutions USA, Inc Molecular Imaging 2501 N. Barrington Road Hoffman Estates, IL 60192 USA

AUG 16 2013

Date of Submission:	June 03, 2013

Identification of the product

Device Proprietary Name:	Symbia 5.0
Common/Classification Names:	Emission Computed Tomography per 21 CFR 892.1200 Computed Tomography X-Ray System per 21 CFR 892.1750
Class:	II
Product Code:	KPS and JAK
Classification Panel:	Radiology

Marketed Devices to which Equivalence is claimed

Device	Manufacturer	510(k) Number
Symbia 4.0	Siemens Medical Solutions USA, Inc.	K082506

Device Description:

The Siemens Symbia 5.0 systems consist of Single Photon Emission Computed Tomography (SPECT) scanners and integrated hybrid X-Ray Computed Tomography (CT) and SPECT scanners. The SPECT subsystem images and measures the distribution of radiopharmaceuticals in humans for the purpose of determining various metabolic (molecular) and physiologic functions within the human body and integrates CT's anatomical detail for precise reference of the location of the metabolic activity. The CT component produces cross-sectional images of the body by computer reconstruction of X-Ray transmission data from either the same axial plane taken at different angles or spiral planes taken at different angles. The system can be used as an integrated SPECT and CT modality while also enabling independent functionality of SPECT and CT as stand-alone diagnostic imaging devices.

The Symbia 5.0 consists of Symbia E,.S, T, Intevo Excel and Intevo systems.

- The Symbia E Series and Symbia S are SPECT only systems.
- The Symbia T Series are SPECT/CT systems.
- The Symbia Intevo Excel is a non-diagnostic SPECT/CT system with CT support for only attenuation correction and anatomical localization.
- The Symbia Intevo Series are xSPECT systems. These are SPECT and CT systems integrated through xSPECT technology during image registration and reconstruction. This xSPECT integration enables the use of extra-modal information for high image quality and quantification.

For all systems, a new software version syngo MI Applications VA70 and optional LPHR collimator for I-123 imaging are available.

Indications for Use:

The Siemens Symbia series is intended for use by appropriately trained health care professionals to aid in detecting, localizing, diagnosing, staging and restaging of lesions, tumors, disease and organ function for the evaluation of diseases and disorders such as, but not limited to, cardiovascular disease, neurological disorders and cancer. The images produced by the system can also be used by the physician to aid in radiotherapy treatment planning and interventional radiology procedures.

SPECT: To detect or image the distribution of radionuclides in the body or organ, using the following techniques: planar imaging, whole body imaging, tomographic imaging for isotopes with energies up to 588keV

CT: The CT component is intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data from either the same axial plane taken at different angles or spiral planes taken at different angles.

SPECT+CT: Perform CT scans and nuclear imaging studies with the same instrument. To obtain attenuation corrected images and to provide registration of anatomical and physiological images within the patient's anatomy.

Software: The MI Applications software is a display and analysis package intended to aid the clinician in the assessment and quantification of pathologies taken from SPECT, PET, CT and other imaging modalities.

Performance Testing:

Symbia 5.0 conforms to applicable FDA recognized and international IEC, ISO and NEMA standards with regards to performance and safety as required by the respective SPECT FDA Guidance Documents. SPECT detector and CT performance is conducted according to NEMA NU2:2007, and the performance does not change from the predicate device. LPHR performance testing is conducted according to NEMA NU-1:2007. Finally, image quality testing is conducted for LPHR and xSPECT features, and all image quality testing results meet expected image quality requirements.

Risk Management is ensured via a risk analysis in compliance with ISO 14971:2007 to identify and provide mitigation to potential hazards beginning early in the design cycle and continuing throughout the development of the product. Siemens Medical Solutions, USA Inc. adhere to recognized and established industry standards such as IEC 60601-1 series to minimize electrical and mechanical hazards.

The device labeling contains instructions for use and any necessary cautions and warnings to provide for safe and effective use of the device.

Substantial Equivalence:

The Symbia 5.0 device has the same intended use and utilizes the same fundamental scientific technology as the predicate device. The difference lies in the new reconstruction algorithm, xSPECT, which is based on the existing reconstruction algorithm of the predicate device. xSPECT enables the use of extra-modal information for high image quality and SPECT quantification. In addition, there are improvements to the rear PHS, update software, and a new optional LPHR collimator.

These changes do not affect the fundamental scientific technology of the device, and Siemens considers Symbia 5.0 to be as safe, as effective, and with performance substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Ms. Elaine Chang, RAC
Regulatory Technical Specialist
Siemens Medical Solutions USA, Inc.
810 Innovation Drive
KNOXVILLE TN 37932

August 16, 2013

Re: K131634
Trade/Device Name: Symbia 5.0
Regulation Number: 21 CFR 892.1200 / 21 CFR 892.1750
Regulation Name: Emission computed Tomography System
/ Computed Tomography x-ray System
Regulatory Class: Class II
Product Code: KPS / JAK
Dated: June 3, 2013
Received: June 4, 2013

Dear Ms. Elaine Chang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael D. O'Hara

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Indications for Use

510(k) Number (if known): K131634

Device Name: Symbia 5.0

Indications for Use:

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SPECT: The SPECT component is intended to detect or image the distribution of radionuclides in the body or organ (physiology), using the following techniques: planar imaging, whole body imaging, and tomographic imaging for isotopes with energies up to 588 keV.

CT: The CT component is intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data (anatomy) from either the same axial plane taken at different angles or spiral planes taken at different angles.

SPECT+CT: The SPECT and CT components used together acquire SPECT/CT images. The SPECT images can be corrected for attenuation with the CT images, and can be combined (image registration) to merge the patient's physiological (SPECT) and anatomical (CT) images.

Software: The syngo MI Applications software is a display and analysis package intended to aid the clinician in the assessment and quantification of pathologies in images produced from SPECT, PET, CT, and other imaging modalities.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k) ___K131634_____